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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/730,617	12/05/2000	Catherine Burgess	15966-609 (CURA-109)	7404

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EXAMINER

WEGERT, SANDRA L

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/730,617

Applicant(s)

BURGESS ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,60,65,67 and 69-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,60,65,67 and 69-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendment filed 18 December 2002 (Paper No. 16) has been entered. Claims 2, 3, 56-59, 61-64, 66 and 68 are cancelled. Claims 1, 60, 65 and 67 were amended. Claims 69-72 were added. Claims 1, 60, 65, 67 and 69-72 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Objections/Rejections

Withdrawn Objections and/or Rejections

Title

The objection to the title as set forth at p. 2-3 of the previous Office Action (Paper No. 15, 18 September, 2002) is *withdrawn* in view of the amendment which introduced a new title (Paper No. 16, 18 December, 2002).

URL's

The objection to the specification because it contained browser-executable code, as set forth at p. 3 of the previous Office Action (Paper No. 15, 18 September, 2002) is *withdrawn* in view of the amendment which removed all hypertext links from the disclosure (Paper No. 16, 18 December, 2002).

35 USC § 112, first paragraph- Scope of Enablement

The rejection of Claims 2, 3, 56-59 and 61-66 under 35 U.S.C. 112, first paragraph- is *withdrawn in part*. The reasons for this rejection were set forth at pages 7-10 of the previous Office Action (Paper No. 15, 18 September, 2002). Applicants amended independent claims so that they no longer refer to variants that are at least 90% identical to SEQ ID NO: 4 (Paper No. 16, 18 December, 2002).

35 USC § 112, first paragraph- Written Description

The rejection of Claims 59 and 65 under 35 U.S.C. 112, first paragraph- Written Description- is *withdrawn*. The reasons for this rejection were set forth at pages 12-14 of the previous Office Action (Paper No. 15, 18 September, 2002). Applicants cancelled claim 59 and amended claim 65 to remove reference to *allelic variants* (Paper No. 16, 18 December, 2002).

Maintained Objections and/or Rejections

35 U.S.C. § 101/112, first paragraph-, Lack of Utility, Enablement.

Claims 1, 60, 65, 67 and 69-72 are rejected under 35 U.S.C. 101, because the claimed Invention lacks patentable utility. The reasons for this rejection under *35 U.S.C. § 101* were set forth at pp. 3-12 of the previous Office Action (Paper No. 15, 18 September, 2002). Claims 41, 60, 65, 67 and 69-72 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a

well established utility for the reasons set forth in the previous Office Action, one skilled in the art clearly would not know how to use the claimed invention.

The claims are directed to a polypeptide that possesses 70-90% homology to known neuromedin-like peptides, such as the Neuromedin B precursor protein (2002, Krane, et al, Accession No. P08949) and Human Bombesin-like peptide (1988, Krane, et al, J.B.C, 263(26): 13317-13323). As discussed in the previous Office Action (p. 4), no well-established utility exists for newly isolated complex biological molecules. The specification does not disclose experiments that impart *any* function for the neuromedin polypeptide in the context of the cell or organism. The specification does not teach the skilled artisan how to use the peptide for any unique or specific purpose. For example, there is no specific disclosure of the use of the polypeptide as a neurotransmitter or hormone, or of changes in proliferative processes in transfected cells (see, for example: Ferris, et al, 1997, J.C.I., 100(10): 2530-2537), or the phenotypes of "knock-in" or "knock-out" organisms, or of diseases caused by an overactivity or underactivity of the peptide. The skilled artisan is not provided with sufficient guidance to use the claimed polypeptide for any purpose.

Applicants argue (p. 4, Paper No. 16, 18 December, 2002) that the claimed polypeptide has sufficient utility as a marker for *cell-proliferative diseases*, based on tissue-expression panels (Specification: Tables 4 and 5). Applicant's arguments filed 18 December 2002 have been fully considered but they are not persuasive. As discussed in the previous Office Action (Paper No. 15, 18 September, 2002) the asserted functions for the claimed polypeptide are neither

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substantial nor specific. The specification discloses a wide range of tissues that express the polypeptide of SEQ ID NO: 4. Applicants have demonstrated that the polypeptide of SEQ ID NO: 4 in the instant application is expressed in various tissues, including the adrenal gland, thyroid gland, brain neurons, brain glia, mammary glands, and several human cancer cell lines and primary cultures. Applicant states that this expression pattern supports a useful function of the polynucleotide encoding SEQ ID NO: 4 as a diagnostic marker for proliferative diseases. However, as discussed in the previous Office Action (Paper No. 15, 18 September, 2002), one skilled in the art would not readily use the nucleotides encoding the claimed polypeptide for tissue-typing in a real world sense as the protein is not specific to one tissue or type of tissue and is not associated with any disease or disorder.

In fact, the polypeptide is expressed inconsistently in cancer tissues. It is found at high levels in one strain of colon cancer, and is low in two other colon cancer cell lines. It is expressed in moderate levels in one line of breast cancer cells, and is very low in two others; in fact, the level of expression is highest in *normal* breast tissue. Similarly, the polypeptide is expressed in a wide variety of cancerous tissues, but reaches highest expression levels in normal tissues such as adrenal gland, thyroid and testis. With the wide range of tissue types showing high expression of the polynucleotide encoding SEQ ID NO: 4, and the lack of correlation with a specific disease, it would be difficult to envision use of the polynucleotide encoding SEQ ID NO: 4 as a diagnostic marker for any proliferative disease.

Applicants further argue (p. 5, Paper No. 16, 18 December, 2002) that the polypeptide of the instant Specification is a neuromedin, based on high homology with other neuromedins and

based on the presence of a Bombesin consensus sequence W-A-x-G-[SH]-[LF]-M, and that homology of the disclosed polypeptide with a class of proteins *already having* utility shall impart sufficient utility on the novel polypeptide. However, the polypeptide of the Instant Specification, despite bearing 70-90% homology to other peptides is, as yet, unidentified as to a *specific* function. Other Bombesin-like molecules may be categorized as having general types of hormonal roles in an organism, but each has a unique specific function, dictated by the receptor it binds to and subsequent transduction processes (see, for example: Ferris, et al, 1997, J.C.I., 100(10): 2530-2537). Applicants have not disclosed any function unique to the one polypeptide of SEQ ID NO: 4.

Furthermore, despite the Applicant's arguments (p. 5, Paper No. 16, 18 December, 2002) the Utility Guidelines make clear that the usefulness of new polypeptides does not include functions typical of *families* of proteins, stating: "where a class of proteins is defined by common structural features, but evidence shows that the members of the class do not share a specific, substantial functional attribute or utility despite having structural features in common, membership in the class may not impute a specific, substantial, and credible utility to a new member of the class" (Federal Register, 2001, 66(4): 1094). There is no evidence that the protein disclosed in the instant Specification functions as a Bombesin, neuromedin or neuromedin precursor protein. However, even if it were established as such, additional specific functional assays would be needed since this family of proteins is diverse, with a variety of functions ascribed to its members (Whitley, et al, 1999, J. Mol. Endocrinol. 23: 107-116; Akesson, et al, 1997, JBC, 272(28): 17405-17409; Fujii, et al, 2000, JBC, 275(28): 21068-21074). Furthermore, function of a peptide is often not predictable from the amino acid

sequence. Mutant hormones and peptide neurotransmitters are often incapable of binding to receptors or transducing signals (see, for example: Tokita, et al, 2001, JBC, 276(1): 495-504). These examples and others demonstrate that one skilled in the art would not know the utility and function of the polypeptide disclosed in the instant disclosure, even if it *were* classified as a neuromedin because, as discussed in the related art above and the Specification of the instant Application: their effects include "modulation of smooth muscle contraction, exocrine and endocrine processes, metabolism, and behavior" (p. 2 of Specification).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

3/17/03

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER